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FDA Law Update

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Reverse Payments - Hot Button Issue

The issue of a patent litigation settlement in the form of payments by a brand name drug company to the defendant to delay marketing a generic version of its brand name counterpart is heating up this summer. Indeed, it is currently both before the Supreme Court and Congress.

A group of indirect purchasers filed a petition with the Supreme Court seeking review of the Federal Circuit's decision in *In Re:Ciprofloxacin* finding that Bayer's $398 million payment to Barr and Hoechst Marion Roussel (now Sanofi-Aventis) to delay marketing a generic version of a drug did not violate federal antitrust laws. Arkansas Carpenters Health and Welfare Fund is asking the court to determine whether reverse payments to settle patent litigation are *per se* lawful without regard to the amount paid or strength of the underlying patent challenge. This is the third time the issue of reverse payments has been brought to the Supreme Court. The Court refused to hear the prior two cases.

Should the Supreme Court decide to hear this case, its decision will resolve a current split among the Circuit Courts regarding the legality of reverse payments. The U.S. Court of Appeals for the Sixth Circuit has held that such payments are illegal; the Second and Federal Circuits have upheld them. The Eleventh Circuit adopted a more nuanced stance, holding that reverse payments should be analyzed under the antitrust rule of reason.

In the present case for which Supreme Court review is sought, the Federal Circuit concluded that reverse payments to settle patent litigation do not violate antitrust law as long as (1) the suit is not a sham or otherwise baseless; and (2) the settlement does not impose restrictions on the alleged infringer that extend beyond the scope of the patent. It remains to be seen whether the Supreme Court will grant the petition to review this decision and settle the current split.

Recently, private class action suits also have been filed against these reverse payment settlements. The most recent class action against these companies marks the 11th private suit concerning this reverse payment settlement agreement. The United Food and Commercial Workers Union and Employers Midwest Health Benefits Fund filed a putative class action suit in the District of Minnesota, seeking to recover what it called overcharges stemming from the "unlawful delay and exclusion" of generic AndroGel. The unlawful delay and exclusion was a result of Unimed making payments to Watson, Par, and Paddock in exchange for keeping their less expensive generics off the market. Prior to this class action, the FTC and state of California

both sued Watson, Par, Paddock, and Unimed in California claiming that the reverse payment was unlawful. The case was subsequently transferred to the Northern District of Georgia, where the case is still pending.

Notably, its not just the Judiciary that is currently grappling with the reverse payment issue. The issue is also now before Congress. The House Judiciary Committee's Courts and Competition Policy Subcommittee held a hearing on June 3, 2009 regarding reverse payments and the proposed Protecting Consumer Access to Generic Drugs Act of 2009 (H.R. 1706). At this hearing, FTC Bureau of Competition Director Richard A. Feinstein testified in support of the bill stating the Commission strongly supports the Protecting Consumer Access to Generic Drugs Act of 2009 (H.R. 1706), which would prohibit these reverse settlement ("anticompetitive settlements"). Feinstein further opined stated that this legislation would "subvert the goals of the Hatch-Waxman Act, which was designed to prevent weak patents from obstructing lower-cost generic competition." Over the years, the Federal Trade Commission has consistently opposed reverse payments but its court challenges of them have been unsuccessful.

Also testifying at the June 3rd Congressional hearing, Guy T. Donatiello, Vice President of Intellectual Property at Endo Pharmaceuticals, voiced opposition to the bill stating H.R. 1706 would discourage settlement and instead force companies to engage in patent disputes that they otherwise would not, costing consumers. Bret M. Dickey, Senior Vice President of Economic Consulting firm Compass Lexecon, concurred with Donatiello and testified that patent settlements can benefit consumers by keeping litigation costs and risk of litigation low.

Notably, on the same day as the House Judiciary Committee hearing, the House Energy and Commerce Committee, Commerce, Trade, and Consumer Protection Subcommittee approved this same bill (H.R. 1706) with a 16 to 10 vote, sending it to the full Committee for further action. Subcommittee members did, however, express concern that the bill could inadvertently result in less access to generic drugs. Representative Joseph R. Pitts (R-Pa.) said brand drug companies will have no incentive to settle cases, thus further expressing concern that, generic companies may only challenge a patent if a positive outcome is highly likely. An amendment proposed by Representative George P. Radanovich (R-Calif.) and approved by a voice vote of the Subcommittee, requires the Government Accountability Office to conduct a study two years after the legislation is enacted to analyze the impact of the legislation on patent litigation. The analysis will be focused on whether generics actually enter the market earlier as a result and if there are any resulting harm or benefits to consumers. The bill will now go to the Energy and Commerce Committee for markup.

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